

MAY - 8 2000

K0004/6

May 14, 2000

**Premarket Notification [510(k)] Summary**

**Submitter:** RetinaLabs.com, Inc.  
1776 Peachtree Street Suite 200 North  
Atlanta, GA 30309

**Phone:** (404) 815-5233  
**Fax:** (404) 873-3582

**Official Correspondent:** Frank J. Tighe

**Trade Name:** The RetinaLabs.com, Inc., TransPak

**Common Name:** Vitreoretinal Infusion Pak

**Registration Number:** 1063514

**Class:** Class 2

**Class Name:** We were unable to find the device listed in the classification regulations, 21 CFR Parts 862-892 [807.87 (c)].

**Panel:** Ophthalmic

**Product Code:** MPA

**Device Description:** The RetinaLabs.com, Inc. TransPaks are paks containing cannulae for infusing saline and manipulating the retina during vitreoretinal surgery.

The components will be offered in an Integrated Pak, as well as available individually. Other previously approved 510K devices will also be included in variations of the integrated pak. Examples: Moistair Humidifier 510K=K974561, and Endo-Illuminator 510K=K970875) Please see Device Replica Diagram in Appendix B.

### **Statement of Indications for Use**

**Integrated Infusion Pak** - For infusing balanced saline and retinal manipulation during vitreoretinal ophthalmic surgery.

**Infusion Cannula** - For infusing balanced saline during vitreoretinal ophthalmic surgery.

**Manipulator** - For retinal manipulation during vitreoretinal ophthalmic surgery.

(Other previously approved 510K devices included in an the integrated pak will be subject to their previously approved indications for use.)

### **Substantial Equivalence Comparison**

	<b><u>American Medical Devices, Inc.</u></b>	<b><u>Visitec</u></b>
Packaging		
Tyvek Lid to Polymylar Sheath.	X	X
For saline infusion.	X	X
Materials:		
Stainless Cannula/ Silicone Tubing	X	X

### **Sterility**

The Device will be ETO Sterilized.

The method used to validate the sterilization cycle is AAMI Overkill Method.

Packaging Material:Tyvek Lid to Polymylar Sheath..

The SAL is 10 to the -6.

The maximum levels of residues of ethylene oxide: 25 parts per million; ethylene chlorohydrin: 25 parts per million and ethylene glycol: 250 parts per million.

This device is non-pyrogenic and the LAL Method is used to make that determination.

**Pyrogens:** We control the manufacturing environment to lessen the likelihood of pyrogen causing bacteria. In addition the LAL Method is used to determine that each lot is non-pyrogenic.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Frank Tighe  
Retinalabs.com  
1776 Peachtree Street  
Suite 200 North  
Atlanta, GA 30309

Re: K000416  
Trade Name: TransPak (Vitreoretinal Infusion Pak)  
Regulatory Class: II  
Product Code: 86MPA (Ophthalmic Fiberoptic Light Pipe)  
Regulation: 876.1500  
Dated: February 4, 2000  
Received: February 8, 2000

Dear Mr. Tighe:

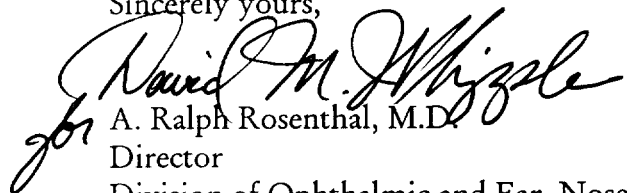
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the [kit/tray] have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in cursive script, appearing to read "David M. Whizzle".

A. Ralph Rosenthal, M.D.

Director

Division of Ophthalmic and Ear, Nose and  
Throat Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

K 000 416



510(k) Number: N/A

Device Name: TransPak (Vitreoretinal Infusion Pak)

**Indications for Use:**

Integrated Infusion Pak - For infusing balanced saline and retinal manipulation during vitreoretinal ophthalmic surgery.

(Infusion Cannula - For infusing balanced saline during vitreoretinal ophthalmic surgery.)

(Manipulator - For retinal manipulation during vitreoretinal ophthalmic surgery.)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

E. Bennett  
(Division Sign-Off)  
Division of Ophthalmic Devices  
510(k) Number K000416

OP

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